FINAL/APPROVED (06/05/2006)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

Wednesday, March 8, 2006
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:12 a.m.

PRESIDING: Leo H. Ross, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
Toni Aust
John O. Beckner
Willie Brown
Bobby Ison
David C. Kozera
Diane Langhorst
Michael E. Stredler

MEMBERS ABSENT: Mark A. Oley

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Ralph Orr, Program Manager, Prescription Monitoring Program
Tiffany N. Mallory, Administrative Assistant

QUORUM: With nine members of the Board present, a quorum was established.

Ms. Reiniers-Day went over the emergency evacuation procedure.

WELCOME: Ms. Russell welcomed Tiffany N. Mallory as the newest member of the Board of Pharmacy staff.

APPROVAL OF AGENDA: There was one addition to the agenda. Ms. Russell requested a petition for rulemaking be added to the agenda. Mr. Brown moved to adopt the agenda. Hearing no other changes, Mr. Ross approved the agenda with the one addition.

APPROVAL OF MINUTES: The minutes of the December 1, 2005 Board Meeting were approved as presented.

PUBLIC COMMENT: No public comments were received.

LEGISLATIVE UPDATE:

Ms. Yeatts reviewed legislative actions of the 2006 General Assembly that the Department of Health Professions had been tracking.

UPDATE ON REGULATION PROCESSES

Ms. Yeatts presented the board with an overview of all ongoing regulation processes.

ADOPTION OF FINAL REGULATIONS FOR WHOLESALE DISTRIBUTORS

Ms. Yeatts stated that the only comment on the proposed regulations had been submitted by Board staff that the first paragraph of section 18VAC110-20-630 regarding medical equipment suppliers had been inadvertently stricken when moving language from chapter 20 to chapter 50 and needed to be added back to chapter 20 upon adoption of final regulation. The addition would not change any current requirements and would clarify the current requirement for an application to be submitted to request a new permit or to change location of an existing permit. Mr. Beckner moved and the Board voted unanimously, to adopt as final regulations for wholesale distributors the proposed regulations as published with the amendment to add back suggested language for medical equipment suppliers to 18VAC110-20-630. (amended section included as Attachment 1)

ADOPTION OF FINAL EXEMPT REGULATIONS ON RETURNED CHECK FEE AMENDMENT:

Ms. Yeatts stated that Virginia law now establishes a fee of $35 for all returned checks. This puts the Board's fee of $25 in chapter 20 in conflict with the statute. For this reason the Board can amend its fee through an exemption to the APA. The change would affect section "H" of 18VAC110-20-20 to increase the returned check fee from $25 to $35. She also stated that there is no returned check fee in 18VAC110-30-15, which is the fee list for practitioners selling controlled substances. Ms. Yeatts proposed to increase the returned check fee in chapter 20 and add the fee to chapter 30 of the regulations to bring the Board's rules in conformity with law. Mr. Beckner moved and the board voted unanimously to adopt the exempt regulation for the returned check fee of $35 in both chapters 20 and 30.

PETITION FOR RULE-MAKING

Ms. Russell commented that she had received a petition for rule-making from Meron Endale. Ms. Russell stated that the petition is not clear as it references several sections of regulations that do not relate to the summary of the substance of the requested change, and that she planned to contact the individual to determine exactly the requested change. It appears that the requested change relates to the Board accepting practical experience hours once a foreign graduate has been approved to take the FPGEE, but without he or she being registered as a pharmacy intern. The petition will be sent directly to the registrar for publication. Ms. Yeatts stated that the board had 14 days to reply to the applicant and put the petition out for comment. According to Ms. Yeatts, the Board would then have ninety days after the comment period has ended to determine what action it wants to take with respect to the petition. This

matter will be placed on the June meeting agenda for action.

APPROVAL OF GUIDANCE DOCUMENT 110-36 ON USP 797 DEADLINE

Ms. Russell stated that the current deadline for compliance with physical requirements of USP Chapter 797 in guidance document 110-36 was originally based on the deadline established by JACHO. However, according to a recent email, which was presented by Ms. Russell, JACHO is no longer enforcing that deadline. Ms. Russell had a concern that if JACHO had backed off on the deadline, then the board may want to reconsider enforcing the June 30, 2007 deadline or push it back. There was discussion as to what would be a reasonable time frame.

Sammy Johnson, Deputy Director of Enforcement commented that many of the pharmacies did not know how or what needed to be done in order to be in compliance with 797. Mr. Johnson also suggested that guidance from the board would help with the inspection process.

Ms. Russell suggested that an ad hoc committee could look at the entire guidance document for needed changes. Mr. Ison moved to have the Chair appoint a subcommittee to review the guidance document for needed amendments or clarifications, and the Board approved the motion unanimously. Mr. Ross asked for volunteers to serve on the subcommittee. Mr. Ison, Ms. Abernathy, and Mr. Stredler were appointed to serve on the ad hoc committee. The committee will meet before the next board meeting.

APPROVAL OF A GUIDANCE DOCUMENT ON DISPENSING FROM MOBILE UNITS

As follow-up to the December Board meeting Ms. Juran presented a draft guidance document to the Board for review for which Ms. Langhorst, Mr. Kozera, and Ms. Aust had individually provided guidance. It allows permitted physicians to store and dispense drugs to the indigent and underserved via mobile units upon certain conditions. Ms. Juran reminded the Board that it had been decided in the December meeting that pharmaceutical services were not reasonably available to the indigent and underserved, and that mobile units may not meet current regulations regarding physical, storage and security standards. Therefore, a committee had been appointed to draft a guidance document to serve as a stopgap until regulations could be amended to allow for this recognized need. Ms. Langhorst suggested that the terms “indigent” and “underserved” be defined. Ms. Langhorst also suggested a periodic report from the board because she felt this was new territory and that the board could not anticipate every concern within this guidance document. There was also some discussion about accommodating mobile vans that did not return to its home base each night. Ms. Russell stated that this may be an issue the Board will have to address in the future, but that at this time the applicants did not request to be able to do this. She suggested that the Board wait until it receives such a request before trying to establish conditions under which it would allow

overnight stays. Ms. Abernathy commented that she wanted to hear back from the applicants and welcome any of their comments.

Also, there was some concern about the language related to a generator source to maintain controlled room temperature that did not require any type of alarm to alert someone if the generator malfunctioned. Ms. Russell suggested to delete the language "have a generator source which will" and just require the mobile unit to maintain drugs at controlled room temperature allowing the licensee to determine how to do this. Mr. Beckner moved, and the board unanimously voted to adopt the draft guidance document, with the amended room temperature language, allowing for physicians to store and dispense drugs to the "indigent" and "underserved" as defined by federal guidelines which board staff will add to the document. (amended document with requested definitions Attachment 2)

GUIDANCE DOCUMENT FOR NEW ONE-YEAR LIMIT ON SCHEDULE VI PRESCRIPTION REFILLS

Ms. Russell stated that the board had received several comments concerning confusion with the recent regulatory change to the life of a schedule VI prescription. VPhA has requested a guidance document clarifying the one-year default limit on schedule VI drugs. There was lengthy discussion as to whether longer than a year needed to be indicated by a time designation, such as refill for two years, refill for fifteen months, or if refills longer than a year could also be designated by a number such as 24 refills, or 99 refills. It was decided that "prn" refills meant one year, 99 refills meant two years, and any other number refills greater than the number needed for one year meant a maximum of two years limited to that number of refills. The Board determined that a guidance document was not needed, that pharmacists should use professional judgment in making a determination about the prescriber's instructions, and asked staff to address the topic in the upcoming electronic newsletter.

REQUEST ALLOWANCE FOR A U.S. ARMY HOSPITAL IN KOREA TO PROVIDE PRACTICAL EXPERIENCE TO PHARMACY INTERNS, BOTH U.S. GRADUATES AND FOREIGN GRADUATES

Ms. Russell presented an email received from Tou T. Yang who currently works in a U.S. army hospital located outside the United States. Mr. Yang requested that the board approve that particular hospital to be a site for students to gain their hours of experience. Board counsel was concerned if the request met the interpretation of the Board's regulations. Mr. Yang stated that currently there are three Virginia licensed pharmacists working at that location. Ms. Russell stated that current regulations require practical experience to be gained within the United States, but that it would appear a U. S. military institution would be considered to be within the U.S. The regulations also require that experience gained in "another state" be registered with and certified by that state board. This would not appear to be possible in a military institution in another country, and that the Board may want to

consider this request in the course of its upcoming regulatory review. Mr. Casway stated that if the Board wanted to allow this, it could possibly construe that the army could act as a state board for the purpose of registering and certifying the hours. Ms. Russell stated that this is problematic because she is not aware of any entity in the army that serves a function similar that of a state board. Mr. Beckner questioned whether this situation had been approved by any other state board. Ms. Russell stated that she did not have this information but could obtain it. Ms. Abernathy questioned whether this would be a good topic to discuss at the upcoming NABP conference. Ms. Yeatts stated that the Board may want to consider this issue separately from the regulation review process because that process may take longer. Ms. Russell stated that because this is new, because there is not any entity in place currently to certify the hours, and because there are many questions, that the Board may want to spend some time researching whether this is something it wants to allow. Other comments included the fact that although there are three Virginia pharmacists there now, this may not always be the case; the fact that while this army hospital may be a good site for practical experience, others may not be; and the fact that this request is coming from one army hospital and does not appear to be a coordinated request from the U. S. Army, and that persons higher in command may not even be aware of this request. Ms. Russell suggested that the Board survey other states through NABP to obtain a more complete answer, and to respond to Mr. Yang that his request is not allowed under current regulations, but that it would be considered during the upcoming review. Mr. Ison moved, and the Board voted unanimously, to accept Ms. Russell's recommendation.

REPORT ON THE BOARD OF HEALTH PROFESSIONS

Ms. Aust briefly reviewed for the Board the most recent meeting of the Board of Health Professions. She reported that during the meeting, there was discussion concerning increasing training for board members. Currently, training occurs once at the beginning of a new Board member's term, but there is no ongoing training opportunity which may be needed.

EXECUTIVE DIRECTOR'S REPORT

Ms. Russell reported that 93% of pharmacy technicians and 95% of pharmacist renewed online during this past renewal period.

She stated that she, Ms. Abernathy, and Mr. Kozera will be attending the NAPB annual meeting in April, and they will report back to the Board.

Ms. Russell is still planning to have a retreat in September. The last retreat was held at the Hampton-Inn in Lexington. Ms. Russell commented that this was a reasonable location, and requested any suggestions for other locations. The retreat will last for two days around the already established date of September 27,

and the board meeting will take place either the first or last day. Mr. Beckner suggested the Hotel Roanoke. Ms. Langhorst requested that the retreat take place on a Wednesday and Thursday, which is the 27 and 28 of September. Ms. Russell commented that she will look into having a facilitator present at the retreat.

Ms. Reiniers-Day gave a report regarding the Board's disciplinary caseload and stated that, 239 cases were at enforcement level, 36 at APD, and 89 at the Board level. Ms. Abernathy asked if there were any new trends. Ms. Reiners-Day in response stated that we are seeing more cases involving unregistered persons working as pharmacy technicians. Also, there has been an increase in the number of applications for registration as a non-resident pharmacy from North Carolina pharmacies. Currently North Carolina does not conduct opening or routine inspections on a regular basis. The Board has been allowing a type of self-inspection process, but that will probably end as of June 30 when the new law goes into effect allowing the Board to accept inspections from other entities. Ms. Russell stated that the Board will need to consider what other types of inspections they will allow before the law takes effect.

Ms. Juran reviewed with the board the number of current active and current inactive licensees as of March 6, 2006. It was noted that there were just over 21,000 licensees. She, also, reported on the number of licenses issued by the Board since the December Board meeting. She gave a breakdown of the number of Board of Pharmacy related inspections conducted by the Enforcement Division during 2005. It was noted that approximately one-half of the total number of licensed pharmacies were inspected during 2005, and that approximately 1400 inspections had been conducted.

Ms. Juran then mentioned some additional information which has been added to the website including regulations effective January 11, 2006, frequently asked questions referencing prescription blank requirements that will go into effect July 1, 2006, and a recent change to guidance document 110-7 regarding prescribers prescribing for self and family which mirrors Board of Medicine regulations that became effective in October 2005. Ms. Juran also stated that a committee will meet later this month with Comira, the new contractor for the Pharmacy Drug Law exam. It will review the job analysis and the current item bank, as well as draft new items.

Mr. Orr reviewed with the board the implementation schedule for the Prescription Monitoring Program. As of February 27, 2006 the database held 1,680,320 records. A contract has been signed with Optimum Technology, Inc., who will collect and manage all the data for the program. The program is expected to go statewide by

June 2006. Mr. Orr also reviewed with the board the new federal Combat Methamphetamine Act which sets requirements for sale of OTC ephedrine and pseudoephedrine products, some of which are more stringent than current state requirements.

NEW BUSINESS: Ms. Russell stated that it is time to begin scheduling meetings to conduct the periodic review of the regulations. She stated that committees would be formed to review specific areas of regulation. She requested that the Board members email Ms. Juran preferred dates, and any interest that they may have in a particular committee. She also mentioned that any interested parties in the public could ask to be included on these committees, and that such information should be communicated to Ms. Juran. Ms. Russell commented that the June 7, 2006 board meeting may need to be moved to a later date due to the DEA annual conference June 6th through June 8th. No decision was made in moving the next board meeting at this time.

ADJOURN: With all business concluded, the meeting adjourned at 12:35 p.m.

Elizabeth Scott Russell
Executive Director

Leo H. Ross, Board Chair

Date

18VAC110-20-630. ~~Licenses and permits generally.~~ [~~(Repealed)~~ Issuance of a permit as a medical equipment supplier.]

~~A license or permit shall not be issued to any manufacturer, wholesale distributor, warehouser, or medical equipment supplier to operate from a private dwelling, unless a separate business entrance is provided, and the place of business is open for inspection at all times during normal business hours. The applicant shall comply with all other federal, state and local laws and ordinances before any license or permit is issued.~~

[A. Any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the board on a form approved by the board. An application shall be filed for a new permit, or for acquisition of an existing medical equipment supplier.

B. A permit holder proposing to change the location of an existing license or permit or make structural changes to an existing location shall file an application for approval of the changes and schedule an inspection to be conducted by an authorized agent of the board.

C. A permit shall not be issued to any medical equipment supplier to operate from a private dwelling, unless a separate business entrance is provided, and the place of business is open for inspection at all times during normal business hours. The applicant shall comply with all other federal, state and local laws and ordinances before any license or permit is issued.]

Virginia Board of Pharmacy
Mobile Units for Dispensing for the Indigent or Underserved Population

For good cause shown and pursuant to 54.1-3304, the Board of Pharmacy may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. The Board has recently interpreted that the indigent and medically underserved may represent a population for which pharmacy services are not reasonably available. As such, a physician desiring to dispense drugs only to an indigent or underserved population from a mobile unit may apply for this license as a "permitted physician" which allows him to practice pharmacy pursuant to Board of Pharmacy regulations as set forth in 18VAC110-20-410. For purposes of this guidance document, "indigent" is defined as those persons whose income is not more than 200% above the federal poverty guidelines, and a medically underserved area or population is defined by criteria established by the Health Resources and Services Administration of the U.S. Department of Health and Human Resources.

Additionally, pursuant to 18VAC110-20-120, the Board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. While 18VAC110-20-410 does not specifically reference 18VAC110-20-120, the Board interprets that it may also waive certain requirements for permitted physicians if the services provided are of a special or limited nature. The Board has been made aware of at least two physicians who use mobile units traveling throughout a community to offer medical assistance to the indigent or underserved and who would like to include the dispensing of prescription drugs. Mobile units do not meet all physical requirements of 18VAC110-20-150 for security and appropriate storage conditions for drugs, and possibly do not meet the alarm requirements of 18VAC110-20-180. They also may not meet the traditional enclosure requirements of 18VAC110-20-190.

The Board recognizes that there is a growing need to be able to provide pharmacy services to this population. Therefore, if a physician applies for a permitted physician license for this purpose, he may request a waiver of sections A, B and C of 18VAC110-20-150, but must be able to meet the other requirements of this section including temperature control. The enclosure requirements in a mobile unit may, if approved after inspection, be met by a separate lockable room, compartment, or cabinet. In order for the Board to consider waiving these requirements for a mobile unit, the following criteria must be met in addition to all other legal requirements for a permitted physician:

- The mobile unit shall not stock any Schedule II-V controlled substances for dispensing.
- The mobile unit shall be parked daily during its off-hours at the same designated location as specified to the Board during the application process.
- When parked during the off-hours, the mobile unit shall be under camera surveillance or within a secure parking area with around-the-clock security staff, and in an area that is affiliated with the physician’s practice location.
- The mobile unit shall at all times provide a controlled temperature environment pursuant to 18VAC110-20-150.
- The mobile unit shall have an alarm system that complies with the requirements of 18VAC110-20-180 and capable of alerting the alarm company or security staff to any breaking. It shall fully protect the drug storage area and shall only be controlled by the physician or designated personnel authorized to dispense medications. It shall be activated and operational at all times the mobile van is not in use to include any breaks during the day when it is not staffed.
- The mobile unit shall only be used to serve the indigent or underserved consistent with the permitted physician application.
- If the mobile unit is to be parked and not used for more than seven consecutive days, all drugs for dispensing must be removed from the unit and stored in a permanent location where access is restricted to the permitted physician.

An application for a limited-use pharmacy permit for a mobile unit for this same purpose would also have to meet the same requirements.